REMARKS:

Reconsideration of the rejections set forth in the Final Office Action mailed July 20, 2009 and entry of the present amendment is requested because Applicants respectfully submit that the present Amendment places the application in condition for allowance or in better form for consideration on appeal.

In response to the Final Office Action, claims 1, 21, and 25 have been amended, and new claim 31 has been added. The amendments are fully supported by the original disclosure, for example, in the specification, e.g., at page 41, lines 1-7 and between page 71, line 13 and page 72, line 5, and in the drawings, e.g., in FIGS. 11D-11F and FIGS. 12A-12B. No new matter has been introduced.

In the Final Office Action, claims 1, 6-7, 25, and 28-30 were rejected under 35 U.S.C. § 103(a) as unpatentable over U.S. Patent No. 6,045,570 ("the Epstein reference") in view of U.S. Publication No. 2002/ 0193808 ("the Belef reference"), claims 2-5 were rejected under 35 U.S.C. § 103(a) as unpatentable over the Epstein reference in view of the Belef reference and further in view of U.S. Patent No. 5,626,601 ("the Gershony reference"), claims 8-10 were rejected under 35 U.S.C. § 103(a) as unpatentable over the Epstein reference in view of the Belef reference and further in view of U.S. Patent No. 6,562,059 ("the Edwards reference"), claims 21-23 were rejected under 35 U.S.C. § 103(a) as unpatentable over the Gershony reference, claim 24 was rejected under 35 U.S.C. § 103(a) as unpatentable over the Gershony reference in view of the Belef reference, and claims 26-27 were rejected under 35 U.S.C. § 103(a) as unpatentable over the

Epstein reference in view of the Belef reference and further in view of U.S. Patent No. 6,162,240 ("the Cates reference").

Because none of the cited references, either alone or in combination, discloses, teaches, or suggests the subject matter of the present claims, the rejections should be withdrawn.

Turning first to the Epstein reference, a closure device 21 is disclosed that includes a tubular member 22 including a main lumen 26 and a second lumen 27 communicating with a port 28 on the distal extremity 24. Col. 4, line 66 to col. 5, line 13. A closure assembly 32 is carried by the distal extremity 24 of the tubular member 22 and is coupled to a deployment mechanism 33 for movement from a contracted to an expanded position. Col. 5, lines 28-33. The deployment mechanism 33 includes a push-pull wire 41 extending from the closure assembly 32 out the proximal extremity 23 of the tubular member 22 and connected to a handle 44. Col. 5, line 65 to col. 6, line 10. A button 47 on the handle 44 is slidably mounted in a slot 49 for moving the closure assembly 32 between the contracted and expanded positions. Col. 6, lines 14-24. Thus, the handle 44 does not include a piston slidably disposed within a chamber nor a reservoir filled with inflation media. Instead, the closure device 21 merely includes a push-pull wire arrangement that moves the closure assembly 32 from the contracted to the expanded position.

The Epstein closure device 21 also includes biological sealant means 81 carried by the handle 44 and in communication with the second lumen 27 for delivering sealant components via the external port 28. Col. 7, lines 1215; col. 6, lines 28-43. During use, the closure device 21 is inserted into "a conventional over-lying sheath 111" already in a puncture 106 extending to a vessel lumen 104 with the closure assembly 32 in the retracted position. Col. 8, lines 59-60, col.

9, lines 6-10; FIG. 5A. Once the distal extremity 24 of the tubular member 22 is exposed in the lumen 104, the sheath 111 is withdrawn, and the button 47 is retracted to expand the closure assembly 32. Col. 9, lines 10-23, 36-44. The closure device 21 is then retracted until the closure assembly 32 contacts the vessel wall 103 to form a seal. Col. 9, lines 54-60; FIG. 5B.

A sealant 116 is then delivered through the second lumen 27 of the tubular member 22 and "through the exit port 28 which is adjacent the closure assembly 32." Col. 10, lines 35-44; FIG. 5C. Once the sealant has assumed the desired state, the button 47 is moved within the slot 49 to retract the closure assembly 32 back into the tubular member 22, and the closure device 21 is removed from the puncture 106. Col. 11, lines 3-16.

Turning to the present claims, claim 1 recites an apparatus for sealing a puncture extending through tissue that includes a tubular member having a proximal end, a distal end sized for insertion into the puncture, and a lumen extending between the proximal end and an outlet at the distal end; an elongate occlusion member slidably disposed within the tubular member, the occlusion member comprising a proximal end, and a distal end extending distally through an opening in the distal end of the tubular member; an expandable member on the occlusion member distal end; a delivery device coupled to the proximal end of the tubular member, the delivery device comprising a plunger that is advanceable to deliver a sealing compound from the tubular member lumen around the occlusion member and from the outlet at the distal end of the tubular member; and a retraction assembly coupled to the proximal end of the tubular member and to the occlusion member, the retraction assembly comprising a lock for securing the tubular member in a distal position relative to the occlusion member, and a trigger that is activated by

advancement of the plunger to thereby disengage the lock, the retraction assembly being biased to retract the tubular member proximally relative to the occlusion member when the lock is disengaged while delivering the sealing compound from the tubular member lumen out the outlet at the distal end of the tubular member.

As conceded on the first full paragraph on page 3 of the Final Office Action, the Epstein reference fails to disclose, teach, or suggest anything about a retraction assembly.

However, the Epstein reference is completely deficient to render the present claims obvious for other reasons as well. In paragraph 10 bridging pages 10 and 11, the Final Office asserts that the tubular member recited in claim 1 is met by 111, which is confirmed in the Advisory Action dated November 12, 2009. The Epstein reference expressly teaches that 111 is a ***conventional over-lying sheath*** 111, col. 8, lines 59-60, and that the sheath 111 is withdrawn completely from the puncture 106 either before or after deploying the closure assembly 32, col. 9, lines 21-30, FIG. 5B. In either case, however, sealant 116 is not delivered until the closure assembly 32 has established a good seal with the wall 103 of the puncture 106, col. 10, lines 25-32, i.e., after the sheath 111 has been completely withdrawn from the puncture.

Although the Epstein sheath 111 is arguably a tubular member, ***a delivery device*** comprising a plunger to deliver a sealing compound is not ***coupled to the proximal end*** of the sheath 111, as recited in claim 1. Instead, the Epstein sealant means 81 (the only structure including a plunger as part of syringe 86) is coupled to the handle 44 of the closure device 21, and never to the sheath 111. Thus, the sheath 111 cannot constitute the tubular member recited in claim 1 for this reason alone.

This distinction is further reinforced by new claim 31, which expressly recites that that delivery device is coupled to a side port on the proximal end of the tubular member for delivering the sealing compound through the tubular member lumen. As can be clearly seen in FIGS. 5A-5D, the Epstein sheath 111 does not include a side port on its proximal end, nor is the sealant means 81 coupled to such a side port. Instead, the Epstein sealant means 81 is coupled to the handle 44 of the closure device 21.

In addition, the Epstein reference does not disclose, teach, or suggest a delivery device coupled to the proximal end of the tubular member to deliver a sealing compound from the tubular member lumen ***around the occlusion member and from the outlet at the distal end of the tubular member***, as recited in claim 1. As explained above, the Epstein sealant means 81 is coupled to the closure device 21 to deliver sealant 116 from a second lumen 27 of tubular member 22 through a port 28 on the distal extremity 24 of the tubular member 22. The Epstein reference does not teach or suggest delivering the sealant 116 through the sheath 111 nor from an outlet of the sheath 111, and, in fact, the sealant 116 is incapable of being delivered through the sheath 111 since the sealant means 81 is coupled to the tubular device 22 and not the sheath 111.

More particularly, the Epstein reference does not teach delivering the sealant 116 through the sheath 111 ***around*** the closure device 21. Instead, the sealant 116 is delivered through a separate lumen 27 of the closure device 21, i.e., is delivered through the only structure that could arguably considered an occlusion member, as claimed. Finally, the sealant 116 could not be delivered through the sheath 111 because the sheath 111 is already removed from the puncture 106 when the sealant 116 is delivered, as clearly shown in FIG. 5C.

Because none of the other references teaches or suggests a delivery device coupled to the proximal end of a tubular member, the delivery device comprising a plunger that is advanceable to deliver a sealing compound from the tubular member lumen out the distal end of the tubular member, claim 1 and its dependent claims are not obvious over the cited references for these reasons alone.

With respect to the retraction assembly recited in claim 1, the November 12 Advisory Action clarifies that element 5 of the Belef reference is considered an occlusion member. However, element 5 is actually a clip that is delivered using the apparatus 310 to close a puncture. Thus, a person of ordinary skill would consider the Belef clip 5 to be somewhat analogous to the sealing compound of the present claims, since both are delivered into a puncture to close or seal the puncture. Therefore, there would be no rational reason for considering the Belef clip when deciding whether it would be obvious to modify the Epstein reference to include relative motion between the sheath 111 and the closure device 21.

In addition, the Belef clip 5 cannot properly be considered an occlusion member, as recited in claim 1, because, as claimed, the occlusion member includes a proximal end, a distal end, and ***an expandable member on the occlusion member distal end***. The Belef clip 5 clearly does not include an expandable member on its distal end, but merely includes barbs or tines 7 on its distal end. The only arguable expandable member disclosed in the Belef reference is an expandable distal portion 182 of obturator assembly 18. However, the Final Office Action does not identify the expandable distal portion 182 as being the expandable member from claim 1 but identifies this expandable distal portion 182 as being the tubular member recited in claim 1.

Second, the Belef clip 5 cannot satisfy the occlusion member of claim 1 because the occlusion member of claim 1 is slidably disposed within the tubular member and the occlusion member distal end extends distally through an opening in the distal end of the tubular member. The Final Office Action alleges that the tubular member of claim 1 is met by the expandable distal portion 182, which is part of obturator assembly 18. As can be clearly seen in FIG. 1 above, however, the obturator assembly 18 is inserted into sheath 12, which carries the clip 5, and not the other way around. Thus, the Belef clip 5 is incapable of being slidably disposed within the expandable distal portion 182 of the obturator assembly 18.

Finally, as explained in Applicants' previous responses, the Belef device operates in a directly opposite manner to the retraction assembly recited in claim 1. Claim 1 recites that the retraction assembly is biased to ***retract the tubular member proximally relative to the occlusion member*** when the lock is disengaged ***while delivering sealing compound from the tubular member lumen*** out the distal end of the tubular member. As explained at page 72, lines 3-19 of the present application, when the retraction assembly is activated during use, the introducer sheath 90 (a tubular member, as claimed) may be automatically withdrawn proximally from the puncture 190 as the sealing compound 146 is delivered, thereby filling the puncture tract with the sealing compound 146, as shown in FIGS. 11E and 11F. Thus, while the occlusion member maintains temporary hemostasis, the tubular member is retracted proximally away from the occlusion member.

The only structure of the Belef reference that is remotely analogous to the sealing compound recited in claim 1 is the clip 5, since both are intended to seal or close a puncture.

However, the clip 5 is alleged to be the occlusion member of claim 1, and the Belef reference does not teach moving the clip 5 proximally relative to the expandable distal portion 182, but advancing the clip 5 (within the carrier assembly 14) while collapsing and retracting the expandable distal portion 182. This is necessary to avoid driving the tines 7 of the clip 5 into splines 186 of the expanded distal portion 182.

Thus, in direct contrast to claim 1, the Belef reference discloses retracting the obturator assembly 18 (which is the only component that could arguably constitute an occlusion member as recited in claim 1) into a sheath 12. Thus, the Belef reference actually discloses advancing a tubular member relative to an occlusion member, and not retracting a tubular member, as does the retraction assembly of claim 1.

For these reasons, even if the Belef reference could somehow be properly combined with the Epstein reference (which Applicants do not concede), the result would be the opposite configuration of the apparatus of claim 1. Accordingly, claim 1 and its dependent claims are not obvious over the Epstein and Belef references. For similar reasons, claim 25 and its dependent claims are also not obvious over the Epstein and Belef reference.

The Cates reference cannot be properly combined with the other cited references and, even if somehow properly combined, fails to disclose, teach, or suggest the features wholly absent from the other cited references, as explained in Applicants' previous response. Finally, the Edwards reference also fails to provide any additional teaching or suggestion absent from the other cited references to render claims 1 and 25 and their dependent claims obvious.

Turning to the rejections based on the Gershony reference, as conceded in paragraph 6 on page 8 of the Final Office Action, the Gershony reference does not teach a piston. However, without any supporting evidence, the Final Office Action then concludes that "it was well known in the art that an inflation device or delivery comprises [sic] a plunger, piston or syringe activated by an actuator which may be connected to the inflation port 77 or injectate port 79, as taught by Gershony. Directing a plunger or piston proximally would cause" . . . . In the paragraph 12 bridging pages 11 and 12, this statement is repeated without any evidence to support the statement. Such cursory statements are not a clear articulation of the reasons why claim 21 is obvious and therefore fails to present a prima facie case of obviousness. Accordingly, for this reason alone, the rejections based on the Gershony reference should be withdrawn.

Turning to the actual language claim 21, an apparatus is recited for sealing a puncture extending through tissue that includes an outer member comprising proximal and distal ends defining a longitudinal axis therebetween with an inflation lumen extending between the outer member proximal and distal ends, an expandable member comprising proximal and distal ends and having a variable length dimension, the proximal end of the expandable member being coupled to the distal end of the outer member such that an interior of the expandable member is in fluid communication with the inflation lumen, the expandable member being expandable from a collapsed state to an expanded state by introduction of fluid into the interior; an inner member slidably coupled to the outer member and comprising proximal and distal ends, the inner member distal end coupled to the expandable member distal end, the inner member slidable relative to the outer member for moving the distal end of the expandable member towards and away from the

proximal end of the expandable member when the expandable member is expanded and collapsed, respectively; and a housing on the proximal end of the outer member, the housing comprising a chamber in fluid communication with the inflation lumen, a piston slidably disposed within the chamber and coupled to the inner member, a reservoir having a cross-section larger than the inflation lumen filled with inflation media and in fluid communication with the chamber via a relatively narrow passage, and an actuator that may be activated by a user to direct the inflation media from the reservoir into the chamber and inflation lumen, thereby substantially simultaneously expanding the expandable member and directing the piston proximally to thereby pull the inner member proximally to shorten the expandable member as it expands.

First, the Gershony reference does not disclose, teach, or suggest anything about a housing on the proximal end of an outer member, the housing comprising a chamber in fluid communication with the inflation lumen, a piston slidably disposed within the chamber and coupled to the inner member, and a ***reservoir having a cross-section larger than the inflation lumen filled with inflation media*** and in fluid communication with the chamber ***via a relatively narrow passage***. Although the Gershony device 66 includes a hub 70 on a proximal end of shaft 69, the hub 70 does not include either a chamber or a reservoir filled with inflation media, as recited in claim 21, and, in particular, does not include a chamber and a reservoir communicating via a relatively narrow passage, as claimed.

In addition, as explained in Applicants' previous response, the Gershony inflation port 77 communicates with lumen 78, while the core wire 73 is disposed in a completely separate lumen

74 of its own. Thus, introduction of inflation media into the lumen 78 would have absolutely no impact on the core wire 73.

The Advisory Action erroneously states that the Gershony core wire 73 is automatically pulled back when the expandable member expands, referring to FIGS. 3-5 of the Gershony reference. The Gershony reference, however, expressly states that

> Fluid is then injected, via a known inflating means (not shown), into the device 10 through the inflation port 31 until a predetermined amount of balloon 15 inflation is attained as for example is shown in FIGS. 3 and 6. Next, the device 10 is manually pulled slightly proximally back through the introducer sheath 61 so that the balloon 15 abuts the distal end of the sheath 61. The core wire 17 is also manually proximally pulled to flatten the profile of the device 10 and minimize disturbance of blood flow in vessel 56.

Col. 5, lines 51-57.

Based on this passage, clearly, the core wire 17 is not automatically pulled back when the balloon 15 is inflated. Instead, in a subsequent manual step, the core wire is proximally pulled to flatten the balloon 15, as shown in FIG. 3.

Thus, the Gershony reference fails to disclose, teach, or suggest a housing that includes an actuator that may be activated by a user to ***direct the inflation media from the reservoir into the chamber*** and inflation lumen, thereby ***substantially simultaneously expanding*** the expandable member ***and directing the piston proximally*** to thereby pull the inner member proximally ***to shorten the expandable member as it expands***.

Accordingly, for these reasons, claim 21 and its dependent claims are not obvious over the Gershony reference, either alone or if somehow combined with the other cited references.

In view of the foregoing, it is submitted that the claims now presented in this application define patentable subject matter over the cited prior art. Accordingly, reconsideration and allowance of the application is requested.

Applicants hereby petition for any extension of time necessary to make the present response timely. Applicants believe that a two month extension is currently required.

Respectfully submitted,
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